

### **Remarks**

Applicants have received and reviewed the Office Action dated December 5, 2008. Applicants request entry of this amendment and reconsideration of the rejection of the claims.

Claim 9 is cancelled without prejudice or disclaimer. Applicants reserve the right to file a continuation application directed to the subject matter of claim 9.

Claims 1, 5, and 7 have been amended. New claims 10-13 have been added. The amended and new claims are supported throughout the specification.

### **35 U.S.C. § 102(b)**

Claims 1 and 7-9 were rejected under 35 U.S.C. § 102(b) as anticipated by Rockey, US 4,763,653. Claim 9 is cancelled rendering the rejection of this claim moot. Applicants traverse this rejection.

“Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.” Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 1458 (Fed. Cir. 1984); See also, MPEP §2131. Applicants submit that cited reference does not disclose all of the elements of the rejected claims.

Applicants' claim 1 is directed to an implantable gastro-intestinal device comprising: a gastric bypass comprising an inlet and an outlet and comprised of a permeable material; an inflatable chamber attached to the gastric bypass; an esophageal extension attached to the inlet of the gastric bypass, wherein food passes into the gastric bypass through the esophageal extension; a small bowel extension attached to the outlet of the gastric bypass and comprised of a permeable material, wherein the small bowel extension receives material exiting the outlet of the gastric bypass. Claims 7-8 now depend from claim 1.

Applicants submit that Rockey et al patent does not disclose all of the elements of the claims. Rockey et al does not disclose an implantable device with a small bowel extension. The device as described by Rockey et al is disposed in the stomach or alternatively in the small intestine. In addition, the device of Rockey et al is made of impermeable material rather than permeable material as claimed by Applicants. For at least these reasons, the Rockey et al patent does not disclose all of the elements of the claims and Applicants request withdrawal of the rejection on this basis.

**35 U.S.C. § 103(a)**

Claims 5 and 6 were rejected under 35 U.S.C. § 103(a) over Rockey. Claims 3 and 4 were rejected under 35 U.S.C. § 103(a) over Rockey in view of Stack et al., US 2003/0199991. Applicants traverse these rejections.

The recent Supreme Court case, *KSR Int 'I Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1734 (2007), sets forth the legal standard for obviousness. This case reaffirms the analytical framework set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), which mandates that an objective obviousness analysis includes: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; and (3) resolving the level of ordinary skill in the pertinent art. *Id.* at 1734. Secondary considerations such as commercial success, long felt but unsolved needs, or failure of others may also be persuasive.

In rejecting claims under 35 U.S.C. § 103(a), the examiner bears the initial burden of establishing a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Only if this initial burden is met does the burden of coming forward with evidence or argument shift to the appellant. *Id.* at 1445. Obviousness is then determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. *See Oetiker*, 977 F.2d at 1445. One criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that claimed subject matter should be carried out and would have a reasonable likelihood of success viewed in light of the prior art. *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

"It remains important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does". *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). "Hindsight" is inferred when the specific understanding or principal within the knowledge of one of ordinary skill in the art leading to the modification of the prior art in order to arrive at appellant's claimed invention has not been explained. *In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). The claimed subject matter is nonobvious if it involves a number of complex and unpredictable alternatives and there is no reason one of skill

in the art would select one alternative over another. *Ortho-McNeil vs. Mylan, Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008).

Applicants claim 1 is directed to an implantable gastro-intestinal device comprising: a gastric bypass comprising an inlet and an outlet and comprised of a permeable material; an inflatable chamber attached to the gastric bypass; an esophageal extension attached to the inlet of the gastric bypass, wherein food passes into the gastric bypass through the esophageal extension; a small bowel extension attached to the outlet of the gastric bypass and comprised of a permeable material, wherein the small bowel extension receives material exiting the outlet of the gastric bypass. Claims 3-6 from claim 1.

As discussed above, the Rockey et al patent does not disclose all of the elements of the claims. Rockey et al does not disclose an implantable device with a small bowel extension. The device as described by Rockey et al is disposed in the stomach or alternatively in the small intestine. In addition, the device of Rockey et al is made of impermeable material rather than permeable material as claimed by Applicants. Further, with regard to claims 5 and 6, Rockey does not disclose that the inflatable chamber comprises a plurality of adjacent subchambers in fluid communication with each other, wherein the plurality of adjacent subchambers are distributed over at least a portion of the outer surface of the gastric bypass, and wherein the plurality of adjacent subchambers maintain an open volume in the gastric bypass in the absence of compressive forces thereon, and/or wherein the subchambers are arranged in a quasi-geodesic pattern.

Applicants submit that one of ordinary skill in the art would not have a reasonable expectation of success in obtaining the claimed device from the disclosure of Rockey et al. There are just too many variables that have to be changed from the device described in Rockey et al in order to obtain the claimed device with no direction or guidance suggested by Rockey et al. as to which of many options to select. Moreover, the Rockey et al patent specifies that the material of the sleeve be impermeable. One of the objectives of the device of Rockey et al. is to isolate the walls of the stomach from fluids flowing into it by fluid tight engagement with the stomach wall. See col. 4, lines 8-14 and col.4, line 63 to col. 5, line 12. If the device of Rockey et al were permeable it would not function to isolate the stomach wall or prevent digestion of the contents passing through the device. Thus, applicants submit that the disclosure of Rockey et al does not provide a reasonable expectation of success of obtaining the claimed subject matter.

With regard to claims 3 and 4, the deficiencies of Rockey et al are not remedied by reference to Stack. Stack does not disclose a device comprising a gastric bypass and an inflatable chamber. The device of Stack describes a small pouch for restricting food intake and a cage. The cage is described as a large stent like structure to expand the stomach and is not described as an inflatable chamber. In addition, Stack et al does not describe an implantable device comprising a small bowel extension comprised of permeable material. The small bowel extensions described by Stack indicate that they are covered by an impermeable polymer to prevent food and digestive juices from contacting the mucosa of the duodenum. See para 0048 of Stack et al.

Applicants submit that one of ordinary skill in the art would not have a reasonable expectation of success in obtaining the claimed device from the disclosure of Rockey et al in combination with Stack. There are just too many variables that have to be changed from the device described in Rockey and Stack in order to obtain the claimed device with no direction or guidance suggested by either reference. as to which of many options to select. Moreover, both the Rockey et al patent and Stack patent application specify that at least a portion of the device be impermeable. One of the objectives of the device of Rockey et al. is to isolate the walls of the stomach from fluids flowing into it by fluid tight engagement with the stomach wall. See col. 4, lines 8-14 and col.4, line 63 to col. 5, line 12. One of the objectives of the small bowel extension of Stack is to prevent food and digestive juices from contacting the mucosa of the duodenum. If the devices of Rockey et al and Stack were permeable they would not function to isolate the stomach wall or prevent digestion of the contents passing through the device. Thus, applicants submit that the disclosure of Rockey et al in combination with Stack does not provide a reasonable expectation of success of obtaining the claimed subject matter.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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